EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

REDA Instrumente GmbH

Gänsäcker 34
78532 Tuttlingen
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Traumatological Implants and Instruments for HF-Surgery, Endoscopes and accessories according annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	070894 MR2
Certificate unique ID	170742825
Effective date	2019-03-18
Expiry date	2023-05-07
Frankfurt am Main	2019-03-18

Digitally signed by Iarovoi Petru
Date: 2020.05.26 10:54:55 EEST
Reason: MoldSign Signature
Location: Moldova

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 070894 MR2
Certificate unique ID: 170742825
Effective date: 2019-03-18

REDA Instrumente GmbH

Gänsäcker 34
78532 Tuttlingen
Germany

Device family	Device	UMDNS	Class
Traumatological Implants	Bone screws	16-101	IIb
	Bone wires	16-104	IIb
Instrumente for HF-surgery	**Monopolary and Bipolary**		
	HF-Electrode	16-860	IIb
	HF-Adapters	11-494	IIb
	Electrode Holders	11-497	IIb
	Electrodes active, foot controlled	16-206	IIb
Endoscopes and accessories	Endoscopes	11-274	IIa
	Laparoscope	12-291	IIa
	Thoracoscope	14-047	IIa
	Cystoscope	17-145	IIa
	Uretorenoscope	17-690	IIa
	Nephroscope	15-290	IIa
	Arthroscope	10-198	IIa

CERTIFICATE

This is to certify that the company

REDA Instrumente GmbH

Gänsäcker 34
78532 Tuttlingen
Germany

has implemented and maintains a **Quality Management System**.

Scope:
Manufacture Development and distribution of non-sterile surgical instruments, sterilization containers, ENT, dental, neuro- and ophthalmology instruments as well as non-sterile active and inactive medical products for endoscopy, orthopedics, HF electrodes and accessories as well as non-sterile implants for traumatology.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2016
ISO 13485 : 2016

Certificate registration no.	070894 MP2016
Certificate unique ID	170775706
Effective date	2021-05-17
Expiry date	2024-05-16
Frankfurt am Main	2021-04-30

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
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410.90.en Version 1.0

Declaration of Conformity

REDA INSTRUMENTE GMBH

Konformitätserklärung
Declaration of Conformity

REDA INSTRUMENTE GMBH

Gänsäcker 34
78532 Tuttlingen / Germany
Tel.: +49 (0)74 62 / 9445-0
Fax: +49 (0)74 62 / 9445-20
e-Mail: info@reda-instrumente.de

erklärt hiermit unter eigener Verantwortung, dass alle Artikel der Produktgruppe
herewith declare under our own responsibility, that all items of the product group

Instrumente und Geräte für die Chirurgie der Klasse I, IIa + IIb
gemäß unseren Katalogen Standard Chirurgische Instrumente, Titan Instrumente, HF Monopolar und Bipolar, Neuro Chirurgie Instrumente, Dental Instrumente,
Steril Container, Endoskope und Zubehör für flexible und starre Endoskopie

Instruments and Equipment for surgery of Class I, IIa + IIb
in refer to our catalogues General Surgical Instruments, Titanium Instruments, Neuro Surgery Instruments, Dental Instruments, HF Monopolar and Bipolar,
Sterilization Containers, Endoscopes and Accessories for flexible and rigid Endoscopy

klassifiziert gemäß RL 93/42/EWG (M5), Anhang IX, Regel 1, 6, 7 und 11 in Risikoklasse I, IIa + IIb
classified according to MDD 93/42/EEC (M5) annex IX rule 1, 6, 7 and 11 into risk class I, IIa + IIb

unter Berücksichtigung folgender Richtlinie gefertigt wurden:
have been manufactured under consideration of following Council Directive:

EG-Richtlinie 93/42/EWG (M5)
European Medical Device Directive 93/42/EEC (M5)

Angewandtes Konformitätsbewertungsverfahren nach Richtlinie 93/42/EWG (M5), Anhang II.
Die gelisteten Produkte sind konform mit den Grundlegenden Anforderungen des Anhang I der EG-Richtlinie 93/42/EWG (M5) und werden somit

mit CE bzw CE 0297 gekennzeichnet, von uns in Verkehr gebracht

Das Konformitätsbewertungsverfahren der Klassen IIa und IIb wurde durch unsere Benannte Stelle DQS GmbH, Frankfurt, Notified Body Code 0297 durchgeführt.

Applied conformity assessment according Annex II of MDD 93/42/EEC (M5).
The listed products are conform to the essential requirements of the Medical Device Directive 93/42/EEC (M5) Annex I and are therefore placed into market

with CE *or with* CE 0297 *by us.*

The conformity assessment for class IIa and IIb has been performed by our notified body DQS GmbH, Frankfurt, notified body code 0297.

Tuttlingen, February 2020

Regina Hehl
Geschäftsführerin
Managing Director

Thomas Bendo
Quality Manager

GS1 Germany

The Global Language of Business

2019

Participation in the global GS1 system

GS1 Germany hereby confirms that the company

REDA Instrumente GmbH

Tuttlingen

is part of the global GS1 System with the Global Location Number (GLN):

40 63058 00000 8

The GLN ensures the uniqueness of the licensee and entitles him to use the GS1 Standards in all business processes.

GS1 Identification Standards:
GTIN (Global Trade Item Number),
SSCC (Serial Shipping Container Code), etc.

GS1 Data Carrier Standards:
EAN-13, GS1-128, GS1 DataMatrix, etc.

GS1 Communication Standards:
EANCOM®, GS1 XML, EPCIS, etc.

The GS1 Standards comply, among other things, with the following international rules: ISO 9735, ISO/IEC 15418, ISO/IEC 15459, ISO/IEC 18000-3, ISO/IEC 18000-6. The GS1 Codes also meet symbology standards of ISO, EN and DIN.

Therefore, the optimum conditions required for the seamless cross-company, transnational and industry-wide exchange of data and goods along the value chain are met.

GS1 Germany – as a member of the international GS1 community – represents the worldwide applicable GS1 Standards for the German market.

Cologne, 21/01/2019

Thomas Fell
GS1 Germany GmbH

CERTIFICATE

5.2 Angewandte Normen / Used Standards

Folgende Normen wurden für die Entwicklung herangezogen: • EN ISO 13485:2012; Medizinprodukte — Qualitätsmanagementsysteme— Anforderungen für regulatorische Zwecke • EN ISO 15223-1:2012; Medizinprodukte – Bei Aufschriften von Medizinprodukten zu verwendende Symbole, Kennzeichnung und zu liefernde Informationen –Allgemeine Anforderungen • EN 1041:2008; Bereitstellung von Informationen durch den Hersteller von Medizinprodukten • EN ISO 10993-1:2010; Biologische Beurteilung von Medizinprodukten • EN ISO 14971:2012; Medizinprodukte — Anwendung des Risikomanagements auf Medizinprodukte • EN ISO 7153:2001, Chirurgische Instrumente – Metallische Werkstoffe • EN 62366:2008; Medizinprodukte — Anwendung der Gebrauchstauglichkeit auf Medizinprodukte • DIN 58298:2010; Materialspezifikationen • EN ISO 13402:2001 Chirurgische und zahnärztliche Instrumente	*Following standards are used for the design* • *EN ISO 13485:2012; Medical devices — Quality management systems — Requirements for regulatory purposes* • *EN ISO 15223-1:2012; Symbols to be used with medical device labels, labelling and information to be supplied. General requirements* • *EN 1041:2013, Information supplied by the manufacturer of medical devices (includes Amendment A1:2013)* • *EN ISO 10993:2010, Biological evaluation of medical devices* • *EN ISO 14971:2012, Medical devices - Application of risk management to medical devices* • *EN ISO 7153:2001, Surgical instruments - Metallic materials* • EN 62366:2008; Medical devices — Application of usability engineering to medical devices • DIN 58298:2010; Material Composition • EN ISO 13402:2001 Surgical and dental hand instruments

6. Risikoanalyse / *Risk Analysis*

Die Risikoanalyse wird durchgeführt gemäß EN ISO 14971:2012; Medizinprodukte — Anwendung des Risikomanagements auf Medizinprodukte	*Risk analysis is made according to ISO 14971:2012, Medical devices - Application of risk management to medical devices for the whole life-cycle*

6.1 Grey Box / *Grey Box*

Für die chirurgische Instrumente gibt es folgende Funktionen • (Wieder)Aufbereitung • Bereitstellung im OP-Saal • Anwendung • Evakuierung Inputs der Grey Box sind • Krankenhauspersonal • Geräte zur (Wieder)Aufbereitung • Instrumente • Patient • Arzt Output der Grey Box sind: • Zu behandelnder Bereich • Unsteriles Instrument	*Surgical instruments consist of following functions:* • *(Re-)processing containing of cleaning, disinfection and sterilization* • *Provision into the operation room* • *Intended use* • *Evacuation out of the operation room* *Inputs for the grey box are:* • *Hospital staff* • *Means for (re-)processing* • *Used instrument* • *Patient* • *Surgeon* *Output of the grey box are* • *Region of interest / surgery* • *Non-sterile instrument*